



2

RECEIVED
APR 28 2002
No.: GEN-T121C1
Serial No. 09/471,276
TECH CENTER 1600/2900

REMARKS

Claims 1, 4-8, 10-13, 17, and 19-24 are pending in the present application, of which, claims 22-24 are drawn to the elected invention. The Examiner has not granted Applicants' request to include claim 24 in the elected group, grouping it instead with non-elected Group IV. Applicants respectfully argue that the method of producing a polypeptide of claim 24 relies on the polypeptide composition of elected claim 22 whereas the method of claim 7 (Group IV) relies on a polynucleotide composition. It is Applicants' understanding that, under the Patent Office Group policy, claim 24 would have been included in the elected Group II as it relies on the subject matter of that Group.

Amended formal drawings and a substitute specification, including both a marked-up copy and clean copy were included with the election mailed November 20, 2001 ("filed December 18, 2001"). The Examiner has stated that the drawings were not included, but has not indicated whether the substitute specification was included. Accordingly, Applicants have included a marked-up and a clean copy of the substitute specification and the formal drawings with this response. These are described herein.

Claim rejections under 35 U.S.C. § 101 and § 112, paragraph 1:

The Examiner has rejected claims 22 and 23 for allegedly lacking patentable utility under 35 U.S.C. § 101. The Examiner states that the invention is not supported by a specific utility, as the disclosed uses for the claimed polypeptides are applicable to any polypeptides. The Examiner further asserts that no substantial utility has been established for the claimed invention. The claims are also rejected under 35 U.S.C. § 112, paragraph 1, because one skilled in the art would not know how to use the claimed invention.

Applicants respectfully submit that the claimed polypeptide has a specific utility in that it comprises a signal peptide (see the Sequence Listing). The function of a signal peptide is not generally applicable to any polypeptide. While signal peptides have overlapping function, individual sequences are particularly suited to function in combination with particular mature protein sequences, in particular cell types, or for particular cell membranes (see, for example, von Heinjne, G. and Abrahmsen, L., *FEBS Letters* **244**:439-446 (1989); Al-Qahtani, A., *et al.*, *Biochem J* **331**:521-529 (1998); and Blaudeck, N., *et al.*, *J. Bacteriol.* **183**(2):604-610 (2001)).

One of skill in the art would recognize that the claimed sequence would be a useful signal peptide, especially for targeting protein localization in human liver cells (see Examples 13 and 14, pages 32-33, Table V, page 64, and Table VI, page 84 of the substitute specification and the Sequence Listing).

Applicants respectfully assert that the claimed invention also possesses substantial utility as a signal peptide. Signal peptides are commonly used in the art to effect secretion, subcellular localization or membrane localization of a polypeptide of interest. See for example, the description on page 3, lines 17-29; in Example 48, starting on page 143; and in Example 60, page 162 of the substitute specification. As additional support for this utility, the commercially available pDisplay and pSecTag vectors include the Ig-kappa signal peptide to direct protein localization (Invitrogen catalog numbers V660-20 and V900-20, respectively). Signal peptides are known to be useful for easing production and purification of an otherwise cytoplasmic protein (page 3, lines 27-29) or to develop a screen for protein interactions and potential drugs. This is a credible, well-established utility, as evidenced by the existence of commercially available expression vectors designed to produce signal peptide fusion proteins.

Applicants further submit that one skilled in the art would know how to use the claimed polypeptide. The above discussion provides evidence that uses for signal peptides are known in the art. In addition, Examples 14, 48, and 60, starting on pages 32, 143, and 162 of the substitute specification, respectively, provide specific methods for confirming signal peptide activity and designing targeted fusion proteins.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §101. Moreover, as one skilled in the art would know how to use the claimed invention, Applicants request reconsideration and withdrawal of claim rejections under USC §112, first paragraph.

Sequence Disclosure:

In the action mailed September 25, 2001, the Examiner objected to the presence of nucleotide sequences in Figure 5 and elsewhere, as these sequences are allegedly not listed in the paper copy and computer readable form (CRF) of the Sequence Listing. The Examiner further objected that the sequence identifier "SEQ ID NO:X" must be used in the drawing or in the Brief Description of the Drawings.

Applicants respectfully request cancellation of Figure 5 in response to the Examiner's objection.

Drawings:

Applicants respectfully request cancellation of Figures 6-9, in addition to Figure 5. Applicants respectfully assert that the cancelled figures are unnecessary for understanding of the present invention. Original Figure 10 has been amended to reflect that it is now Figure 5. Figures 1-4 and newly amended Figure 5 have been corrected to comply with the Draftsperson's objections. Applicants request entry of Figures 1-5, which are included in the present response.

Specification:

Applicants request entry of the enclosed substitute specification. The substitute specification, not including the Claims or Sequence Listing, is filed in compliance with 37 CFR 1.125. No new matter has been added. A marked-up copy of the original application reflecting the changes made is included in the present response. The following changes have been made to the original specification: the "Brief Description of Drawings" (page 22) has been amended to reflect cancellation of Figures 5-9; the reference to Figure 10 (page 92) has been amended to reflect the change to Figure 5; the paragraph on pages 154, line 32 through page 155, line 7 is amended to remove reference to cancellation of Figure 5; and the section titled "Example 61" (pages 164-174) has been amended to reflect cancellation of Figures 6-9.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 NW 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/jaj

Attachments: Al-Qahtani, A., *et al.*, *Biochem J* **331**:521-529 (1998)
Blaudeck, N., *et al.*, *J. Bacteriol.* **183**(2):604-610 (2001)
Clean Version of Substitute Specification [177 pages]
Marked-Up Version of Substitute Specification [177 pages]
Substitute/Formal Drawings [5 sheets]